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Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

TEVA BRANDED
PHARMACEUTICAL PRODUCTS
R&D, INC., NORTON (WATERFORD)
LTD., and TEVA
PHARMACEUTICALS USA, INC.

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

DECLARATION OF LIZA M. WALSH

Electronically Filed

- I, Liza M. Walsh, hereby declare as follows:
- 1. I am an attorney admitted to practice before this Court and a partner with the law firm Walsh Pizzi O'Reilly Falanga LLP, counsel for Plaintiffs Teva

Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"). I am fully familiar with the facts set forth herein.

- 2. I submit this Declaration in support of Teva's Motion to Dismiss Counts 1–10 of Defendants' Counterclaims (ECF No. 12).
- 3. Attached as **Exhibit 1** is a true and correct copy of Amneal Pharmaceuticals of New York, LLC's Notice of Paragraph IV Certification of U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,022,509, 10,022,510, 10,086,156, 10,561,808, 10,695,512 and 11,395,889, Concerning ANDA No. 211600 for Albuterol Sulfate Inhalation Aerosol, 90 mcg Per Actuation, and Detailed Factual and Legal Basis of Non-Infringement, Unenforceability, and/or Invalidity, dated August 24, 2023.
- 4. Attached as **Exhibit 2** is a true and correct copy of Chapter 5 "Inhalation and Nasal Drug Products—General Information and Product Quality Tests," *United States Pharmacopeia-National Formulary* (Official Date: Aug. 1, 2023).
- 5. Attached as **Exhibit 3** is a true and correct copy of excerpts from *Approved Drug Products with Therapeutic Equivalence Evaluations*, Food and Drug Administration (44th ed. 2024).

I declare that the foregoing statements made by me are true.

Dated: January 26, 2024 Respectfully submitted,

/s/ Liza M. Walsh

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